Keith J. Miller, Esq.
ROBINSON MILLER LLC
One Newark Center, 19th Floor
Newark, NJ 07102
Telephone: (973) 690-5400
kmiller@rwmlegal.com

*Attorneys for Plaintiffs Genentech, Inc., Biogen, Inc., Hoffmann-La Roche Inc., and City of Hope*

**IN THE UNITED STATES DISTRICT COURT**

**FOR THE DISTRICT OF NEW JERSEY**

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| GENENTECH, INC., a Delaware corporation, BIOGEN, INC., a Delaware corporation, HOFFMANN-LA ROCHE INC., a New Jersey corporation, and CITY OF HOPE, a California not-for-profit organization,<br><br>Plaintiffs,<br><br>v.<br><br>CELLTRION, INC., a Korean corporation, CELLTRION HEALTHCARE CO., LTD., a Korean corporation, TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, and TEVA PHARMACEUTICALS INTERNATIONAL GmbH, a Swiss corporation,<br><br>Defendants. | Case No.<br><br>**COMPLAINT FOR: PATENT INFRINGEMENT; DECLARATORY RELIEF**<br><br>**DEMAND FOR JURY TRIAL** |

Pursuant to Local Civil Rule 10.1, the address of Plaintiff Genentech, Inc. ("Genentech") is 1 DNA Way, South San Francisco, California, 94080. The address of Plaintiff Biogen, Inc. ("Biogen") is 225 Binney Street, Cambridge, Massachusetts, 02142. The address of Plaintiff City of Hope is 1500 East Duarte Road, Duarte, California, 91010. The address of Plaintiff Hoffmann-La Roche Inc. ("Roche") is 150 Clove Road, Little Falls, New Jersey, 07424. The

address of Defendant Celltrion, Inc. ("Celltrion") is 23, Academy-ro, Yeonsu-gu, Incheon, Korea. The address of Defendant Celltrion Healthcare, Co. Ltd. ("Celltrion Healthcare") is 23, Academy-ro, Yeonsu-gu, Incheon, Korea. The address of Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is 1090 Horsham Road, North Wales, PA 19454-1090. The address of Defendant Teva Pharmaceuticals International GmbH ("TPIG") is Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

Plaintiffs Genentech, Biogen, Roche, and City of Hope (individually or collectively, "Plaintiffs") by their undersigned attorneys, for their Complaint against Celltrion, Celltrion Healthcare, Teva, and TPIG (individually or collectively, "Defendants") allege as follows:

## NATURE OF THIS ACTION

1. This is an action for patent infringement arising under 28 U.S.C. § 1331 and the United States Patent Act, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(e)(2), and an action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, seeking a declaratory judgment of patent infringement.

2. The claims for patent infringement brought in this action are necessitated by Defendants' stated intent to import, market, and sell in New Jersey and throughout the United States a copy of Genentech and Biogen's groundbreaking medicinal product, Rituxan®, which aids millions of patients in their fight against debilitating and life-threatening diseases, including blood cancers such as Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia, as well as Rheumatoid Arthritis and Vasculitis, which are chronic and painful autoimmune diseases. First approved in 1997, Rituxan® is proven to improve both the length and quality of life for patients with these and other diseases and has been recognized internationally for its pioneering effect on patients' lives and medicine in general.

3. Such benefits and success did not come quickly or easily. Genentech and Biogen invested many years of work and many hundreds of millions of dollars into developing and testing Rituxan® and ensuring that the product is both safe and effective. Those investments include, *inter alia*, years of laborious and expensive clinical trials that were required before

medical professionals could use Rituxan® to help their patients—clinical trials on which the U.S. Food and Drug Administration ("FDA") relied in making Rituxan® the first monoclonal antibody approved for therapeutic use in fighting cancer in the United States.

4. In contrast, Defendants have piggybacked on Plaintiffs' investments and success and seek to profit from a copied version of Rituxan®. Claiming that their copycat product is "biosimilar" to Rituxan®, Defendants have not borne the expense of conducting their own clinical trials—instead relying on Genentech and Biogen's costly and time-consuming proprietary clinical trials—and have applied to the FDA for approval to market and sell that product.

5. Irrespective of whether they are able to secure FDA approval for its copy of Rituxan®, however, Defendants do not have the right to infringe Plaintiffs' patents. Defendants' intended activities would unquestionably infringe many of those patents, *none* of which Plaintiffs have licensed to Defendants and *all* of which are valid and enforceable. Plaintiffs bring this action to stop that infringement.

## PARTIES

6. Plaintiff Genentech, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 DNA Way, South San Francisco, California, 94080.

7. Plaintiff Biogen, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 225 Binney Street, Cambridge, Massachusetts, 02142.

8. Plaintiff City of Hope is a California not-for-profit organization, having its principal place of business at 1500 East Duarte Road, Duarte, California, 91010.

9. Plaintiff Hoffmann-La Roche Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 150 Clove Road, Little Falls, New Jersey, 07424.

10. Genentech and Biogen, two pioneers of the biotechnology industry, have been

discovering, developing, manufacturing, and commercializing innovative therapies to address significant unmet medical needs for more than 40 years. Collectively, they manufacture and commercialize products for a variety of medical conditions, including numerous types of cancer, Rheumatoid Arthritis, Multiple Sclerosis, and many other serious conditions. Genentech and Biogen developed and jointly market Rituxan®, the revolutionary antibody-based medicine at issue in this case.[1]

11. Founded in 1913, City of Hope is a leading research hospital that incorporates cutting-edge research into patient care for cancer, diabetes, and other serious diseases.

12. Plaintiffs regularly seek patents on inventions originating from their research and development activities, and each has been issued numerous patents relating to its proprietary technology. Among those patents are several that claim, *inter alia*, the manufacture and use of Rituxan®.

13. Plaintiffs are informed and believe, and on that basis allege, that Defendant Celltrion, Inc. is a corporation organized and existing under the laws of the Republic of Korea, having its principal place of business at 23 Academy-ro, Yeonsu-gu, Incheon, 406-840, South Korea. Plaintiffs are further informed and believe, and on that basis allege, that Celltrion is a pharmaceutical company that develops claimed "biosimilars" of biological medicines and, either by itself or through subsidiaries and/or partners, markets and distributes such products around the world, including in the United States.

14. Plaintiffs are informed and believe, and on that basis allege, that Defendant Celltrion Healthcare, Co. Ltd. is a corporation organized and existing under the laws of the Republic of Korea, having its principal place of business at 23 Academy-ro, Yeonsu-gu, Incheon, 406-840, South Korea. Plaintiffs are further informed and believe, and on that basis allege, that Celltrion Healthcare is a pharmaceutical company that develops claimed

[1] Genentech initially collaborated with IDEC Pharmaceuticals, which subsequently merged with Biogen (forming Biogen-Idec) and later adopted the name Biogen. We use "Biogen" herein for simplicity.

"biosimilars" of biological medicines and, either by itself or through subsidiaries and/or partners, markets and distributes such products around the world, including in the United States.

15. Plaintiffs are informed and believe, and on that basis allege, that Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Plaintiffs are further informed and believe, and on that basis allege, that Teva Pharmaceuticals USA, Inc. is a pharmaceutical company that, *inter alia*, develops claimed "biosimilars" of biological medicines and, either by itself or through subsidiaries and/or partners, markets and distributes such products around the world, including in the United States.

16. Plaintiffs are informed and believe, and on that basis allege, that Defendant Teva Pharmaceuticals International GmbH is a limited liability company organized and existing under the laws of Switzerland, having its principal place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland. Plaintiffs are further informed and believe, and on that basis allege, that Teva Pharmaceuticals International GmbH is a pharmaceutical company that develops claimed "biosimilars" of biological medicines and, either by itself or through subsidiaries and/or partners, markets and distributes such products around the world, including in the United States.

## JURISDICTION AND VENUE

17. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* This Court has federal question jurisdiction under 28 U.S.C. § 1331, § 1338(a), 2201(a), and 2202 because this is a civil action arising under the Patent Act.

18. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), including because Defendants are subject to this Court's personal jurisdiction, Defendants have and/or will commit acts of infringement in this district, Celltrion, Inc., Celltrion Healthcare, Co. Ltd., and Teva Pharmaceuticals International GmbH do not reside in the United States, and Teva Pharmaceuticals USA, Inc. has regular and established places of business located in New Jersey.

**A. Celltrion, Inc.**

19. Plaintiffs are informed and believe, and on that basis allege, that this Court has personal jurisdiction over Celltrion because Celltrion has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. In particular, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has taken the costly, significant step of filing an Abbreviated Biologic License Application ("aBLA") with the United States Food and Drug Administration ("FDA") seeking FDA approval of the proposed biosimilar product "Truxima" (also known under the development code "CT-P10") for the express purposes of marketing, distributing, and selling Truxima/CT-P10 in New Jersey and throughout the United States.

20. Plaintiffs are informed and believe, and on that basis allege, that Celltrion and Celltrion Healthcare have entered into a commercial, contractual relationship with Teva and TPIG for the purpose of marketing, distributing, and selling Truxima/CT-P10 in New Jersey and throughout the United States and Canada.

21. Plaintiffs are informed and believe, and on that basis allege, that if and when the FDA approves Celltrion's aBLA for Truxima/CT-P10, Defendants will market, distribute, and sell Truxima/CT-P10 in New Jersey and throughout the United States.

22. In the alternative, Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Celltrion pursuant to Federal Rule of Civil Procedure 4(k)(2) because Celltrion has extensive contacts with the United States, including but not limited to the above-described contacts, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Celltrion is consistent with the laws of the United States and the United States Constitution.

23. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has purposefully established commercial relationships and business dealings with several pharmaceutical companies in the United States, including Teva, Teva subsidiaries, Hospira, Inc., and Pfizer Inc. ("Pfizer"). In addition to Celltrion's aforementioned contractual

relationship with Teva to market, distribute, and sell Truxima/CT-P10, Celltrion and Pfizer are, on information and belief, currently marketing the biosimilar Inflectra® in New Jersey and throughout the United States.

24. In addition, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has availed itself of the benefits of United States law by applying for and obtaining registrations for at least one trademark with the United States Patent and Trademark Office ("PTO") for the word "Truxima," which trademark Celltrion has declared its intent to use in commerce in the United States.

25. Celltrion has further availed itself of the benefits of United States law by filing with the PTO at least ten (10) *inter partes* review petitions challenging Plaintiffs' patents relating to the pioneering biological drug at issue in this case, Rituxan®.

**B. Celltrion Healthcare, Co. Ltd.**

26. Plaintiffs are informed and believe, and on that basis allege, that this Court has personal jurisdiction over Celltrion Healthcare because Celltrion Healthcare has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. In particular, Plaintiffs are informed and believe, and on that basis allege, that Celltrion Healthcare has assisted Celltrion to aid Celltrion in filing an aBLA with the FDA seeking FDA approval of the proposed biosimilar product Truxima for the express purposes of marketing, distributing, and selling Truxima/CT-P10 in New Jersey and throughout the United States. Celltrion Healthcare and Celltrion share the same principal place of business and, on information and belief, Celltrion Healthcare markets, sells, and distributes products developed by Celltrion.

27. Plaintiffs are informed and believe, and on that basis allege, that Celltrion and Celltrion Healthcare have entered into a commercial, contractual relationship with Teva and TPIG for the purpose of marketing, distributing, and selling Truxima/CT-P10 in New Jersey and throughout the United States and Canada.

28. Plaintiffs are informed and believe, and on that basis allege, that if and when the FDA approves Celltrion's aBLA for Truxima/CT-P10, Defendants will market, distribute, and sell Truxima/CT-P10 in New Jersey and throughout the United States.

29. In the alternative, Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Celltrion Healthcare pursuant to Federal Rule of Civil Procedure 4(k)(2) because Celltrion Healthcare has extensive contacts with the United States, including but not limited to the above-described contacts, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Celltrion Healthcare is consistent with the laws of the United States and the United States Constitution.

**C. Teva Pharmaceuticals USA, Inc.**

30. Plaintiffs are informed and believe, and on that basis allege, that this Court has personal jurisdiction over Teva because Teva has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. For example, Plaintiffs are informed and believe, and on that basis allege, that (1) Teva is registered to do business in New Jersey under Entity Identification Number 0100250184 and has appointed a registered agent in New Jersey, Corporate Creations Network Inc., 811 Church Road #105, Cherry Hill, NJ 08002; (2) Teva is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Numbers 5000583 and 5003436; (3) Teva manufactures and distributes brand and generic drugs for sale and use throughout the United States, including in New Jersey; (4) Teva has regular and established places of business in New Jersey, where it has employees and from which it services customers in New Jersey, located at least at 8 Gloria Lane, Fairfield, New Jersey 07004; 400 Chestnut Ridge Rd, Woodcliff Lake, NJ 07677; 208 Passaic Avenue, Fairfield, New Jersey 07004; and 200 Elmora Avenue, Elizabeth, New Jersey 07202; and (5) Teva has additional facilities in New Jersey at least in Elizabeth, Newark, Ewing, Parsippany, and Woodcliff Lake, from which it engages in sales.

31. Plaintiffs are informed and believe, and on that basis allege, that Celltrion and Celltrion Healthcare have entered into a commercial, contractual relationship with Teva and

TPIG for the purpose of marketing, distributing, and selling Truxima/CT-P10 in New Jersey and throughout the United States and Canada.

32. Plaintiffs are informed and believe, and on that basis allege, that if and when the FDA approves Celltrion's aBLA for Truxima/CT-P10, Defendants will market, distribute, and sell Truxima/CT-P10 in New Jersey and throughout the United States.

33. Plaintiffs are informed and believe, and on that basis allege, that Teva has been sued and has litigated in the District of New Jersey, in connection with which it has repeatedly submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey by asserting claims or counterclaims involving pharmaceutical drug patent disputes in this Judicial District in at least the following cases in the past year alone: *Teva Pharms. USA, Inc., et al. v. Sandoz Inc., et al.*, Civil Action No. 17-275; *Teva Pharms. USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 17-517; *BTG Int'l Ltd., et al. v. Teva Pharms. USA, Inc., et al.*, Civil Action No. 17-6435; *Adapt Pharma Operations Ltd., et al. v. Teva Pharms. USA, Inc., et al.*, Civil Action No. 17-5100; *Celgene Corp. v. Par Pharm., Inc., et al.*, Civil Action No. 17-3159; *Adapt Pharma Operations Ltd., et al.* v. *Teva Pharms. USA, Inc., et al.*, Civil Action No. 17-2877; *Adapt Pharma Operations Ltd., et al.* v. *Teva Pharms. USA, Inc., et al.*, Civil Action No. 17-864; *Mitsubishi Tanabe Pharma Corp., et al.* v. *MSN Labs. Private Ltd., et al.*, Civil Action No. 17-5302; *Astrazeneca Pharms. LP, et al.* v. *Teva Pharms. USA, Inc.*, Civil Action No. 17-2448.

**D. Teva Pharmaceuticals International GmbH**

34. Plaintiffs are informed and believe, and on that basis allege, that this Court has personal jurisdiction over TPIG because TPIG has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities.

35. In particular, Plaintiffs are informed and believe, and on that basis allege, that Celltrion and Celltrion Healthcare have entered into a commercial, contractual relationship with Teva and TPIG for the purpose of marketing, distributing, and selling Truxima/CT-P10 in New Jersey and throughout the United States and Canada.

36. Plaintiffs are informed and believe, and on that basis allege, that if and when the FDA approves Celltrion's aBLA for Truxima/CT-P10, Defendants will market, distribute, and sell Truxima/CT-P10 in New Jersey and throughout the United States.

37. In the alternative, Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over TPIG pursuant to Federal Rule of Civil Procedure 4(k)(2) because TPIG has extensive contacts with the United States, including but not limited to the above-described commercial contract, is not subject to jurisdiction in any particular state, and exercising jurisdiction over TPIG is consistent with the laws of the United States and the United States Constitution.

## BACKGROUND FACTS

38. This case relates to the pioneering product Rituxan® and the duly-issued United States patents that cover the manufacture and use of that product. Rituxan® was the first monoclonal antibody approved by the FDA for therapeutic use in fighting cancer and is one of the most successful medicinal products in the world.

39. Plaintiffs are informed and believe, and on that basis allege, that (i) Defendants are engaged in the development of a proposed biosimilar copy of Rituxan®, Truxima/CT-P10, (ii) the aBLA filed by Celltrion seeking FDA approval for Truxima/CT-P10 has named Rituxan® as the reference product that Truxima/CT-P10 is intended to copy, and (iii) the FDA has accepted Celltrion's aBLA for review.

40. Plaintiffs are informed and believe, and on that basis allege, that upon FDA approval Defendants intend to market, distribute, and sell Truxima/CT-P10 in New Jersey and throughout the United States as an alleged biosimilar substitute for Rituxan®.

41. As alleged herein, the manufacture, importation, use, offer for sale, and/or sale of Truxima/CT-P10 infringes one or more patents owned by Plaintiffs, who therefore bring this patent action to address Defendants' infringement and to protect the intellectual property into which they have invested innumerable resources, investments which have redounded to the benefit of the public and medicine in general.

## GENENTECH AND BIOGEN'S RITUXAN® PRODUCT

42. Antibodies are produced by cells of the immune system and are an important component in the immune system's fight against foreign invaders, such as bacteria, viruses, and other microbes and pathogens. In particular, antibodies can bind (attach) to a specific molecular structure that can be present on such foreign invaders or can be present on the body's own cells. A structure to which an antibody binds is called an "antigen." By binding to specific antigens, antibodies help the immune system identify and attack the foreign invaders.

43. Although the human body creates antibodies for various antigens naturally, for several decades scientists have successfully engineered in laboratories antibodies capable of binding to a predetermined antigen, such that the antibodies can be used to develop therapeutic products that target specific medical conditions in humans.

44. In the early 1990s, after many years of research, IDEC Pharmaceuticals (which subsequently merged with Biogen) first created the antibody rituximab (then known as IDEC-C2B8). Researchers at IDEC Pharmaceuticals created rituximab in the laboratory to bind to the human CD20 antigen, a protein expressed on the surface of immune cells called B-cells. By binding to the CD20 antigen, rituximab helps to fight diseases caused or exacerbated by B-cells, including several forms of B-cell cancer.

45. Rituximab is a "chimeric" antibody, meaning that part of its structure is derived from human genetic sequence and part is derived from mouse genetic sequence. Creating this hybrid antibody and studying it in the laboratory, however, was only the beginning of the years-long process required to create an effective yet safe human therapeutic.

46. Following the creation of rituximab, IDEC Pharmaceuticals, Genentech, and F. Hoffmann-La Roche AG, in a tri-company collaboration, spent many years and many hundreds of millions of dollars on scientific studies and clinical trials to develop that therapeutic, which is marketed under the trade name Rituxan® in the United States and MabThera® abroad. They also dedicated enormous time and resources to establish the safety and efficacy of

Rituxan®, to investigate numerous ways to use Rituxan® to treat different diseases, and to determine how to manufacture Rituxan® in sufficient quantity and purity for administration to humans. For example, Rituxan® aids millions of patients in their fight against debilitating and life-threatening diseases, including Non-Hodgkin's Lymphomas (NHLs) and Chronic Lymphocytic Leukemia (CLL), both of which are blood cancers, as well as Rheumatoid Arthritis (RA) and Vasculitis, both chronic and painful autoimmune diseases. Genentech and Biogen continue to dedicate significant time and resources to their ongoing efforts to maximize the effectiveness and use of Rituxan® to benefit patients across the world.

47. Because of its effectiveness against several diseases, including several forms of cancer, Rituxan®/MabThera® has been an enormous commercial success, generating over $7 billion in worldwide revenue in 2016 alone.

48. The innovative work dedicated to creating and developing Rituxan® has been recognized repeatedly by the medical and scientific communities. For example, Rituxan® is on the World Health Organization's List of Essential Medicines (a well-recognized publication that identifies essential medicines for priority diseases) and Plaintiffs have been honored with the Trailblazers Award from the Cure for Lymphoma Foundation and with the Peter McCuen Cancer Research Award for their groundbreaking research and development of Rituxan®.

## THE BPCIA PATHWAY FOR BIOSIMILAR APPROVAL

49. In 1984, Congress created an abbreviated regulatory pathway for the approval of generic small-molecule drugs through the passage of the Hatch-Waxman Act. Small molecule drugs are made from chemicals synthesized in a laboratory and contain both a relatively small number of atoms and a specific, known chemical structure. For example, the active ingredient in aspirin, acetylsalicylic acid, has only 21 atoms. Its chemical makeup and structure is easy to identify and characterize, and it is relatively simple to copy, develop, and manufacture.

50. Biologic agents, like the rituximab antibody in Rituxan®, are much larger and more complex molecules, and are not produced by chemical synthesis in a laboratory. Rather,

they are produced in, and purified from, specially modified living cells, making them extremely difficult to develop and manufacture. Whereas the small-molecule acetylsalicylic acid has only 21 atoms, a complex antibody biologic like rituximab contains about 20,000 atoms. Accordingly, the efforts and investment needed to develop a therapeutic antibody like Rituxan® are significantly greater than for a small-molecule drug like aspirin.

51. In contrast to the abbreviated regulatory pathway for generic small-molecule medicines provided in the Hatch-Waxman Act, no abbreviated pathway for approval of follow-on biologic products existed until the enactment in 2010 of the Biologics Price Competition and Innovation Act ("BPCIA") (codified at 42 U.S.C. § 262) as part of the Patient Protection and Affordable Care Act. As a result, before the enactment of the BPCIA, the only way to obtain FDA approval of a biologic product was through an original Biologic License Application ("BLA") supported by a full complement of pre-clinical and clinical study data. Genentech and Biogen underwent that long, laborious, and expensive process to obtain FDA approval for Rituxan®.

52. The BPCIA's abbreviated pathway for biologic products requires a determination that the proposed product is "biosimilar" to a previously licensed "reference product." 42 U.S.C. § 262(k). The BPCIA defines a "biosimilar" as a biological product that is (1) "highly similar to the reference product notwithstanding minor differences in clinically inactive components" and (2) has "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. §§ 262(i)(2)(A), (B).

53. The BPCIA defines a "reference product" to be a "single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." 42 U.S.C. § 262(i)(4). Here, Rituxan® is the reference product and Truxima/CT-P10 is the proposed biosimilar.

54. Under the BPCIA, biosimilar applicants are permitted to make use of the reference product sponsor's proprietary safety and efficacy data and the FDA's prior

determinations as to the safety, purity, and potency of the already-approved reference product. A biosimilar applicant must identify a single reference product that has already been approved by the FDA and submit to the FDA "publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I).

55. Consequently, the abbreviated regulatory pathway created by the BPCIA allows a biosimilar applicant like Celltrion to avoid the time, expense, and risks of original research and development—as well as the need to conduct a full complement of pre-clinical and clinical testing—required for the submission of an original BLA. The abbreviated pathway thus permits a biosimilar applicant like Celltrion to gain approval to commercialize its biological product much more quickly than if it had undertaken the significant activities required for submission of an original BLA.

## CELLTRION'S PROPOSED BIOSIMILAR PRODUCT TRUXIMA/CT-P10

56. Plaintiffs are informed and believe, and on that basis allege, that on a date prior to June 29, 2017, Celltrion submitted to the FDA an aBLA for Truxima/CT-P10. On or about June 29, 2017, Celltrion and Teva issued a joint press release announcing that the FDA had accepted that aBLA for review. https://www.celltrion.com/en/pr/reportDetail.do?seq=436. More specifically, that press release stated that the FDA had "accepted for review the Biologics License Application (BLA) for CT-P10, a proposed Monoclonal Antibody (mAb) biosimilar to Rituxan® (rituximab), which is used to treat patients with non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), rheumatoid arthritis (RA), granulomatosis with polyangiitis and microscopic polyangiitis." *Id*.

57. Those listed diseases, for which Rituxan® is approved, are the same diseases for which Celltrion sought and received approval in Europe to market CT-P10. *Id*. Plaintiffs are informed and believe, and on that basis allege, that Celltrion is seeking FDA approval to treat those same diseases, i.e., those same "indications," in the United States, thereby seeking FDA

approval for a proposed biosimilar copying Plaintiffs' Rituxan® while intending to market that proposed biosimilar as a substitute treatment for the same medicinal purposes.

**THE BPCIA'S DISPUTE RESOLUTION PROCEDURES**

58. Although the BPCIA provides for an abbreviated regulatory pathway, it does not give biosimilar applicants like Celltrion the right to infringe validly issued patents through, *inter alia*, the manufacture, use, offer for sale, sale, or importation of a biologic product—even if approved by the FDA.

59. Recognizing that valid patents might preclude such activities, the BPCIA established a set of procedures for addressing patent disputes relating to prospective biosimilar products. These procedures are set forth in 42 U.S.C. § 262(l) and 35 U.S.C. § 271 and are intended to ensure that the innovator company whose product serves as the reference product has the opportunity to enforce its patent rights before a biosimilar product enters the market. The procedures are also intended to ensure that disputes over patent rights will take place in an orderly fashion, with the least possible uncertainty, brinksmanship, and burden on the parties and the courts.

60. The BPCIA dispute resolution procedure commences when a biosimilar application is accepted for review by the FDA. Within twenty days thereafter, the biosimilar applicant "shall provide" the reference sponsor with confidential access to "a copy of the [aBLA] submitted" to the FDA "and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(l)(2)(A).

61. After the applicant provides a copy of the aBLA and the required manufacturing information, the BPCIA contemplates a series of pre-litigation exchanges—including of a "list of patents for which the reference sponsor believes a claim of patent infringement could reasonably be asserted by the reference sponsor" regarding the proposed biosimilar, *id*. at § 262(l)(3)(A)(i), and contentions regarding the alleged infringement, non-infringement, invalidity, and

unenforceability of those patents, *id*. at § 262(l)(3)(B)—so that the parties may engage in good-faith negotiations over which patents should be litigated regarding the proposed biosimilar. *See id*. at § 262(l)(2)-(l)(6). These exchanges are colloquially referred to as the "Patent Dance."

**THE PARTIES' EXCHANGES UNDER THE BPCIA**

62. On June 30, 2017, after Celltrion's announcement of the FDA's acceptance for review of the aBLA for Truxima/CT-P10, Plaintiffs requested that Celltrion confirm its intention to provide a copy of that aBLA and the required manufacturing information pursuant to 42 U.S.C. § 262(l)(2)(A) so that Plaintiffs could evaluate whether Truxima/CT-P10 infringes Plaintiffs' patents. Concurrently, Plaintiffs provided Celltrion with a list of exemplary categories of information concerning processes used to manufacture a biological product such as rituximab, information Plaintiffs expected Celltrion to provide so that Plaintiffs could understand the process or processes used to manufacture Celltrion's proposed rituximab biosimilar and determine whether those processes infringe Plaintiffs' patents. In addition, Plaintiffs provided citations to exemplary patents, the content of which clarified the nature of the information Plaintiffs sought for purposes of evaluating possible infringement. A copy of Plaintiffs' letter to Celltrion is attached as Exhibit 41.

63. On or about July 17, 2017, Celltrion provided Plaintiffs with its aBLA for Truxima/CT-P10, but did not meet its obligation to provide "other information that describes the process or processes used to manufacture" Truxima/CT-P10 as required by 42 U.S.C. § 262(l)(2)(A).

64. On August 25, 2017, after Celltrion's deadline for production under 42 U.S.C. § 262(l)(2) but prior to what would have been Plaintiffs' § 262(l)(3)(A) deadline to provide a "list of patents for which the reference sponsor believes a claim of patent infringement could reasonably be asserted by the reference sponsor" if Celltrion had complied with its obligations under 42 U.S.C. § 262(l)(2)(A), Plaintiffs again asked Celltrion to provide the required manufacturing information. Plaintiffs identified a list of missing information and, again, a list of

exemplary patents. Plaintiffs informed Celltrion that—if the requested information was not received—they would assume that the cited patents, and other patents, related to the missing information could reasonably be asserted if Celltrion engaged in making, using, offering to sell, selling, or importing into the United States Truxima/CT-P10.

65. On September 6, 2017, Celltrion declined to provide any additional information.

66. On September 14, 2017, following a meet and confer, Plaintiffs again informed Celltrion that it had not complied with 42 U.S.C. § 262(l)(2)(A) and reserved all of their rights regarding Celltrion's failure to do so. Subject to and without waiver of those reservations, Plaintiffs provided Celltrion with a list of the patents Plaintiffs believed could reasonably be asserted against Truxima/CT-P10 in light of the information provided by Celltrion and given Celltrion's refusal to provide the additional, required information, including those patents that Plaintiffs believed could reasonably be asserted after a reasonable investigation or discovery ("Plaintiffs' Patent List").

67. Two months later, long after the deadline set forth by 42 U.S.C. § 262(l)(2), Celltrion finally produced more than 50,000 pages of new information that Plaintiffs had requested before the deadline. In particular, Celltrion produced such information on or about November 9, 2017, in a production accompanying its purported contentions under 42 U.S.C. § 262(l)(3)(B), alleging that patents on Plaintiffs' Patent List are invalid, unenforceable, or will not be infringed by the commercial marketing of Truxima/CT-P10. In those contentions, Celltrion cites and relies upon this late-produced information in support of non-infringement arguments, thereby demonstrating that such information was, in fact, necessary for evaluating patent infringement and should have been provided earlier pursuant to 42 U.S.C. § 262(l)(2).

68. On January 5, 2018, Plaintiffs again informed Celltrion that it had not complied with 42 U.S.C. § 262(l)(2)(A) and reserved all of their rights regarding Celltrion's failure to do so. Subject to and without waiver of those reservations, Plaintiffs provided to Celltrion a response and detailed statement that describes, with respect to certain patents described in Celltrion's purported 42 U.S.C. § 262(l)(3)(B) list, on a claim by claim basis, the factual and

legal basis of Plaintiffs' opinion that such patent will be infringed by the commercial marketing of Truxima/CT-P10 and a response to Celltrion's statement concerning validity and enforceability. In reliance on representations made by Celltrion in its contentions under 42 U.S.C. § 262(l)(3)(B), Plaintiffs omitted certain patents from its detailed statement but reserved the right to bring suit on such patents if Celltrion refused to produce evidence supporting Celltrion's factual assertions regarding non-infringement.

69. The next step in the Patent Dance would have been for the parties to engage in good faith negotiations to agree on which, if any, patents shall be the subject of an action for patent infringement under 42 U.S.C. § 262(l)(6). But instead of engaging in such negotiations, Celltrion repudiated them. Accordingly, even if Celltrion had complied with its obligations under 42 U.S.C. § 262(l)(2), it failed to comply with its obligations under 42 U.S.C. § 262(l)(4)-(5).

70. Celltrion provided a Notice of Commercial Marketing (the "Notice"), starting a 180-day clock before the first possible date on which Celltrion or its partners could market and/or sell its proposed biosimilar Truxima/CT-P10.

71. Celltrion's failure to provide Plaintiffs with "information that describes the process or processes used to manufacture" Truxima/CT-P10, as required by 42 U.S.C. § 262(l)(2)(A), is particularly prejudicial in light of the Notice of Commercial Marketing, i.e., in light of stated intent to begin marketing its proposed biosimilar of Rituxan® in as few as 180 days.

72. With Celltrion having abandoned all pretext of participating in the Patent Dance, Plaintiffs exercise the right to bring suit pursuant to 42 U.S.C. § 262(l)(9). In the alternative, and/or in addition, Plaintiffs bring suit under 35 U.S.C. § 271(e)(2). Given 42 U.S.C. § 262, Plaintiffs bring suit on all forty patents on the September 14, 2017 Patent List, out of an abundance of caution, to preserve all rights.

## THE ASSERTED PATENTS

73. Plaintiffs have applied for and obtained dozens of issued patents related to Rituxan®, including regarding its therapeutic uses, its administration, its formulation, and the processes by which it is manufactured.

74. Plaintiffs' ability to evaluate Defendants' infringement of their patent estate has been hampered by Celltrion's refusal to provide, *inter alia*, manufacturing information as required by 42 U.S.C. § 262(l)(2)(A). Plaintiffs requested that information multiple times and informed Celltrion that failure to provide it would necessitate legal action. Celltrion continued to evade its statutory obligations.

75. In light of the foregoing, and reserving all rights, Plaintiffs are informed and believe to the best of their present ability, and on that basis allege, that making, using, offering to sell, selling, or importing into the United States Truxima/CT-P10 will infringe, or reasonably could infringe, the following patents (collectively, the "Asserted Patents"), each of which is owned by one or more Plaintiffs and each of which was identified on Plaintiffs' Patent List:

- **U.S. Patent No. 6,121,428**

76. U.S. Patent No. 6,121,428 ("the '428 patent") is entitled "Protein Recovery," was duly and legally issued by the Patent Office on September 19, 2000, and has not expired.

77. One or more Plaintiffs have maintained the entire right, title, and interest in the '428 patent throughout the period of Defendants' infringement. A copy of the '428 patent is attached as Exhibit 1.

- **U.S. Patent No. 6,242,177**

78. U.S. Patent No. 6,242,177 ("the '177 patent") is entitled "Methods and Compositions for Secretion of Heterologous Polypeptides," was duly and legally issued by the Patent Office on June 5, 2001 and has not expired.

79. One or more Plaintiffs have maintained the entire right, title, and interest in the '177 patent throughout the period of Defendants' infringement. A copy of the '177 patent is attached as Exhibit 2.

- **U.S. Patent No. 6,331,415**

80. U.S. Patent No. 6,331,415 ("the '415 patent") is entitled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein," was duly and legally issued by the Patent Office on December 18, 2001, and has not expired.

81. One or more Plaintiffs have maintained the entire right, title, and interest in the '415 patent throughout the period of Defendants' infringement. A copy of the '415 patent is attached as Exhibit 3.

- **U.S. Patent No. 6,417,335**

82. U.S. Patent No. 6,417,335 ("the '335 patent") is entitled "Protein Purification," was duly and legally issued by the Patent Office on July 9, 2002, and has not expired.

83. One or more Plaintiffs have maintained the entire right, title, and interest in the '335 patent throughout the period of Defendants' infringement. A copy of the '335 patent is attached as Exhibit 4.

- **U.S. Patent No. 6,455,043**

84. U.S. Patent No. 6,455,043 ("the ' 043 patent") is entitled "Combination Therapies for B-cell Lymphomas Comprising Administration of Anti-CD20 Antibody," was duly and legally issued by the Patent Office on September 24, 2002, and has not expired.

85. One or more Plaintiffs have maintained the entire right, title, and interest in the '043 patent throughout the period of Defendants' infringement. A copy of the '043 patent is attached as Exhibit 5.

- **U.S. Patent No. 6,489,447**

86. U.S. Patent No. 6,489,447 ("the '447 patent") is entitled "Protein Purification," was duly and legally issued by the Patent Office on December 3, 2002, and has not expired.

87. One or more Plaintiffs have maintained the entire right, title, and interest in the '447 patent throughout the period of Defendants' infringement. A copy of the '447 patent is attached as Exhibit 6.

- **U.S. Patent No. 6,586,206**

88. U.S. Patent No. 6,586,206 ("the '206 patent") is entitled "Methods for Making Recombinant Proteins Using Apoptosis Inhibitors," was duly and legally issued by the Patent Office on July 1, 2003, and has not expired.

89. One or more Plaintiffs have maintained the entire right, title, and interest in the '206 patent throughout the period of Defendants' infringement. A copy of the '206 patent is attached as Exhibit 7.

- **U.S. Patent No. 6,610,516**

90. U.S. Patent No. 6,610,516 ("the '516 patent") is entitled "Cell Culture Process," was duly and legally issued by the Patent Office on August 26, 2003, and has not expired.

91. One or more Plaintiffs have maintained the entire right, title, and interest in the '516 patent throughout the period of Defendants' infringement. A copy of the '516 patent is attached as Exhibit 8.

- **U.S. Patent No. 6,620,918**

92. U.S. Patent No. 6,620,918 ("the '918 patent") is entitled "Separation of Polypeptide Monomers," was duly and legally issued by the Patent Office on September 16, 2003, and has not expired.

93. One or more Plaintiffs have maintained the entire right, title, and interest in the '918 patent throughout the period of Defendants' infringement. A copy of the '918 patent is attached as Exhibit 9.

- **U.S. Patent No. 6,716,602**

94. U.S. Patent No. 6,716,602 ("the '602 patent") is entitled "Metabolic Rate Shifts in Fermentations Expressing Recombinant Proteins," was duly and legally issued by the Patent Office on April 6, 2004, and has not expired.

95. One or more Plaintiffs have maintained the entire right, title, and interest in the '602 patent throughout the period of Defendants' infringement. A copy of the '602 patent is attached as Exhibit 10.

- **U.S. Patent No. 7,381,560**

96. U.S. Patent No. 7,381,560 ("the '560 patent") is entitled "Expression and Use of Anti-CD20 Antibodies," was duly and legally issued by the Patent Office on June 3, 2008, and has not expired.

97. One or more Plaintiffs have maintained the entire right, title, and interest in the '560 patent throughout the period of Defendants' infringement. A copy of the '560 patent is attached as Exhibit 11.

- **U.S. Patent No. 7,390,660**

98. U.S. Patent No. 7,390,660 ("the '660 patent") is entitled "Methods for Growing Mammalian Cells in Vitro," was duly and legally issued by the Patent Office on June 24, 2008, and has not expired.

99. One or more Plaintiffs have maintained the entire right, title, and interest in the '660 patent throughout the period of Defendants' infringement. A copy of the '660 patent is attached as Exhibit 12.

- **U.S. Patent No. 7,485,704**

100. U.S. Patent No. 7,485,704 ("the '704 patent") is entitled "Reducing Protein A Leaching during Protein A Affinity Chromatography," was duly and legally issued by the Patent Office on February 3, 2009, and has not expired.

101. One or more Plaintiffs have maintained the entire right, title, and interest in the '704 patent throughout the period of Defendants' infringement. A copy of the '704 patent is attached as Exhibit 13.

- **U.S. Patent No. 7,682,612**

102. U.S. Patent No. 7,682,612 ("the '612 patent") is entitled "Treatment of Hematologic Malignancies Associated with Circulating Tumor Cells Using Chimeric Anti-CD20

Antibody," was duly and legally issued by the Patent Office on March 23, 2010, and has not expired.

103. One or more Plaintiffs have maintained the entire right, title, and interest in the '612 patent throughout the period of Defendants' infringement. A copy of the '612 patent is attached as Exhibit 14.

- **U.S. Patent No. 7,807,799**

104. U.S. Patent No. 7,807,799 ("the '799 patent") is entitled "Reducing Protein A Leaching during Protein A Affinity Chromatography," was duly and legally issued by the Patent Office on October 5, 2010, and has not expired.

105. One or more Plaintiffs have maintained the entire right, title, and interest in the '799 patent throughout the period of Defendants' infringement. A copy of the '799 patent is attached as Exhibit 15.

- **U.S. Patent No. 7,820,161**

106. U.S. Patent No. 7,820,161 ("the '161 patent") is entitled "Treatment of Autoimmune Diseases," was duly and legally issued by the Patent Office on October 26, 2010, and has not expired.

107. One or more Plaintiffs have maintained the entire right, title, and interest in the '161 patent throughout the period of Defendants' infringement. A copy of the '161 patent is attached as Exhibit 16.

- **U.S. Patent No. 7,923,221**

108. U.S. Patent No. 7,923,221 ("the '221 patent") is entitled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen," was duly and legally issued by the Patent Office on April 12, 2011, and has not expired.

109. One or more Plaintiffs have maintained the entire right, title, and interest in the '221 patent throughout the period of Defendants' infringement. A copy of the '221 patent is attached as Exhibit 17.

- **U.S. Patent No. 7,976,838**

110. U.S. Patent No. 7,976,838 ("the '838 patent") is entitled "Therapy of Autoimmune Disease in a Patient with an Inadequate Response to a TNF-α inhibitor," was duly and legally issued by the Patent Office on July 12, 2011, and has not expired.

111. One or more Plaintiffs have maintained the entire right, title, and interest in the '838 patent throughout the period of Defendants' infringement. A copy of the '838 patent is attached as Exhibit 18.

- **U.S. Patent No. 8,044,017**

112. U.S. Patent No. 8,044,017 ("the '017 patent") is entitled "Protein Purification," was duly and legally issued by the Patent Office on October 25, 2011, and has not expired.

113. One or more Plaintiffs have maintained the entire right, title, and interest in the '017 patent throughout the period of Defendants' infringement. A copy of the '017 patent is attached as Exhibit 19.

- **U.S. Patent No. 8,206,711**

114. U.S. Patent No. 8,206,711 ("the '711 patent") is entitled "Treatment of Chronic Lymphocytic Leukemia using Anti-CD20 Antibodies," was duly and legally issued by the Patent Office on June 26, 2012, and has not expired.

115. One or more Plaintiffs have maintained the entire right, title, and interest in the '711 patent throughout the period of Defendants' infringement. A copy of the '711 patent is attached as Exhibit 20.

- **U.S. Patent No. 8,329,172**

116. U.S. Patent No. 8,329,172 ("the '172 patent") is entitled "Combination Therapies for B-cell Lymphomas Comprising Administration of Anti-CD20 Antibody," was duly and legally issued by the Patent Office on December 11, 2012, and has not expired.

117. One or more Plaintiffs have maintained the entire right, title, and interest in the '172 patent throughout the period of Defendants' infringement. A copy of the '172 patent is attached as Exhibit 21.

- **U.S. Patent No. 8,357,301**

118. U.S. Patent No. 8,357,301 ("the '301 patent") is entitled "Chromatography Equipment Characterization," was duly and legally issued by the Patent Office on January 22, 2013, and has not expired.

119. One or more Plaintiffs have maintained the entire right, title, and interest in the '301 patent throughout the period of Defendants' infringement. A copy of the '301 patent is attached as Exhibit 22.

- **U.S. Patent No. 8,460,895**

120. U.S. Patent No. 8,460,895 ("the '895 patent") is entitled "Method for Producing Recombinant Proteins with a Constant Content of pCO2 in the Medium," was duly and legally issued by the Patent Office on June 11, 2013, and has not expired.

121. One or more Plaintiffs have maintained the entire right, title, and interest in the '895 patent throughout the period of Defendants' infringement. A copy of the '895 patent is attached as Exhibit 23.

- **U.S. Patent No. 8,512,983**

122. U.S. Patent No. 8,512,983 ("the '983 patent") is entitled "Production of Proteins in Glutamine-free Cell Culture Media," was duly and legally issued by the Patent Office on August 20, 2013, and has not expired.

123. One or more Plaintiffs have maintained the entire right, title, and interest in the '983 patent throughout the period of Defendants' infringement. A copy of the '983 patent is attached as Exhibit 24.

- **U.S. Patent No. 8,545,843**

124. U.S. Patent No. 8,545,843 ("the '843 patent") is entitled "Treatment of Vasculitis," was duly and legally issued by the Patent Office on October 1, 2013, and has not expired.

125. One or more Plaintiffs have maintained the entire right, title, and interest in the '843 patent throughout the period of Defendants' infringement. A copy of the '843 patent is attached as Exhibit 25.

- **U.S. Patent No. 8,557,244**

126. U.S. Patent No. 8,557,244 ("the '244 patent") is entitled "Treatment of Aggressive Non-Hodgkins Lymphoma with Anti-CD20 Antibody," was duly and legally issued by the Patent Office on October 15, 2013, and has not expired.

127. One or more Plaintiffs have maintained the entire right, title, and interest in the '244 patent throughout the period of Defendants' infringement. A copy of the '244 patent is attached as Exhibit 26.

- **U.S. Patent No. 8,574,869**

128. U.S. Patent No. 8,574,869 ("the '869 patent") is entitled "Prevention of Disulfide Bond Reduction during Recombinant Production of Polypeptides," was duly and legally issued by the Patent Office on November 5, 2013, and has not expired.

129. One or more Plaintiffs have maintained the entire right, title, and interest in the '869 patent throughout the period of Defendants' infringement. A copy of the '869 patent is attached as Exhibit 27.

- **U.S. Patent No. 8,633,302**

130. U.S. Patent No. 8,633,302 ("the '302 patent") is entitled "Variable Tangential Flow Filtration," was duly and legally issued by the Patent Office on January 21, 2014, and has not expired.

131. One or more Plaintiffs have maintained the entire right, title, and interest in the '302 patent throughout the period of Defendants' infringement. A copy of the '302 patent is attached as Exhibit 28.

- **U.S. Patent No. 8,710,196**

132. U.S. Patent No. 8,710,196 ("the '196 patent") is entitled "Protein Purification," was duly and legally issued by the Patent Office on April 29, 2014, and has not expired.

133. One or more Plaintiffs have maintained the entire right, title, and interest in the '196 patent throughout the period of Defendants' infringement. A copy of the '196 patent is attached as Exhibit 29.

- **U.S. Patent No. 8,771,988**

134. U.S. Patent No. 8,771,988 ("the '988 patent") is entitled "Process for the Production of Gamma-aminobutyric Acid," was duly and legally issued by the Patent Office on July 8, 2014, and has not expired.

135. One or more Plaintiffs have maintained the entire right, title, and interest in the '988 patent throughout the period of Defendants' infringement. A copy of the '988 patent is attached as Exhibit 30.

- **U.S. Patent No. 8,821,873**

136. U.S. Patent No. 8,821,873 ("the '873 patent") is entitled "Treatment of Diffuse Large-cell Lymphoma with Anti-CD20 Antibody," was duly and legally issued by the Patent Office on September 2, 2014, and has not expired.

137. One or more Plaintiffs have maintained the entire right, title, and interest in the '873 patent throughout the period of Defendants' infringement. A copy of the '873 patent is attached as Exhibit 31.

- **U.S. Patent No. 8,822,655**

138. U.S. Patent No. 8,822,655 ("the '655 patent") is entitled "Pre-filtration Adjustment of Buffer Solutes," was duly and legally issued by the Patent Office on September 2, 2014, and has not expired.

139. One or more Plaintiffs have maintained the entire right, title, and interest in the '655 patent throughout the period of Defendants' infringement. A copy of the '655 patent is attached as Exhibit 32.

- **U.S. Patent No. 9,047,438**

140. U.S. Patent No. 9,047,438 ("the '438 patent") is entitled "Chromatography Equipment Characterization," was duly and legally issued by the Patent Office on June 2, 2015, and has not expired.

141. One or more Plaintiffs have maintained the entire right, title, and interest in the '438 patent throughout the period of Defendants' infringement. A copy of the '438 patent is attached as Exhibit 33.

- **U.S. Patent No. 9,080,183**

142. U.S. Patent No. 9,080,183 ("the '183 patent") is entitled "Promoter," was duly and legally issued by the Patent Office on July 14, 2015, and has not expired.

143. One or more Plaintiffs have maintained the entire right, title, and interest in the '183 patent throughout the period of Defendants' infringement. A copy of the '183 patent is attached as Exhibit 34.

- **U.S. Patent No. 9,296,821**

144. U.S. Patent No. 9,296,821 ("the '821 patent") is entitled "Combination Therapies for B-cell Lymphomas Comprising Administration of Anti-CD20 Antibodies," was duly and legally issued by the Patent Office on March 29, 2016, and has not expired.

145. One or more Plaintiffs have maintained the entire right, title, and interest in the '821 patent throughout the period of Defendants' infringement. A copy of the '821 patent is attached as Exhibit 35.

- **U.S. Patent No. 9,428,548**

146. U.S. Patent No. 9,428,548 ("the '548 patent") is entitled "Enhanced Protein Purification through a Modified Protein A Elution," was duly and legally issued by the Patent Office on August 30, 2016, and has not expired.

147. One or more Plaintiffs have maintained the entire right, title, and interest in the '548 patent throughout the period of Defendants' infringement. A copy of the '548 patent is attached as Exhibit 36.

- **U.S. Patent No. 9,428,766**

148. U.S. Patent No. 9,428,766 ("the '766 patent") is entitled "Protein Expression from Multiple Nucleic Acids," was duly and legally issued by the Patent Office on August 30, 2016, and has not expired.

149. One or more Plaintiffs have maintained the entire right, title, and interest in the '766 patent throughout the period of Defendants' infringement. A copy of the '766 patent is attached as Exhibit 37.

- **U.S. Patent No. 9,487,809**

150. U.S. Patent No. 9,487,809 ("the '809 patent") is entitled "Decreasing Lactate Level and Increasing Polypeptide Production by Downregulating the Expression of Lactate Dehydrogenase and Pyruvate Dehydrogenase Kinase," was duly and legally issued by the Patent Office on November 8, 2016, and has not expired.

151. One or more Plaintiffs have maintained the entire right, title, and interest in the '809 patent throughout the period of Defendants' infringement. A copy of the '809 patent is attached as Exhibit 38.

- **U.S. Patent No. 9,504,744**

152. U.S. Patent No. 9,504,744 ("the '744 patent") is entitled "Treatment of Diffuse Large-cell Lymphoma with Anti-CD20 Antibody," was duly and legally issued by the Patent Office on November 29, 2016, and has not expired.

153. One or more Plaintiffs have maintained the entire right, title, and interest in the '744 patent throughout the period of Defendants' infringement. A copy of the '744 patent is attached as Exhibit 39.

- **U.S. Patent No. 9,714,293**

154. U.S. Patent No. 9,714,293 ("the '293 patent") is entitled "Production of Proteins in Glutamine-free Cell Culture Media," was duly and legally issued by the Patent Office on July 25, 2017, and has not expired.

155. One or more Plaintiffs have maintained the entire right, title, and interest in the '293 patent throughout the period of Defendants' infringement. A copy of the '293 patent is attached as Exhibit 40.

**COUNT 1**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,121,428)**

156. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 155 as if fully set forth herein.

157. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

158. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

159. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '428 patent.

160. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

161. The '428 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

162. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '428 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

163. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

164. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '428 patent.

**COUNT 2**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,242,177)**

165. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 164 as if fully set forth herein.

166. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

167. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

168. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '177 patent.

169. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

170. The '177 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

171. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '177 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

172. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

173. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '177 patent.

**COUNT 3**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,331,415)**

174. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 173 as if fully set forth herein.

175. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

176. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

177. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '415 patent.

178. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

179. The ’415 patent claims compositions used in and methods of making a therapeutic antibody product such as Truxima/CT-P10.

180. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’415 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

181. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

182. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’415 patent.

**COUNT 4**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,417,335)**

183. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 182 as if fully set forth herein.

184. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

185. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

186. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’335 patent.

187. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

188. The '335 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

189. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '335 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

190. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

191. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '335 patent.

**COUNT 5**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,455,043)**

192. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 191 as if fully set forth herein.

193. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

194. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

195. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale,

and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '043 patent.

196. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

197. The '043 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

198. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '043 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

199. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

200. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '043 patent.

**COUNT 6**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,489,447)**

201. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 200 as if fully set forth herein.

202. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

203. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

204. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '447 patent.

205. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

206. The '447 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

207. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '447 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

208. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

209. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '447 patent.

## COUNT 7

## (DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,586,206)

210. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 209 as if fully set forth herein.

211. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

212. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10

if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

213. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '206 patent.

214. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

215. The '206 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

216. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '206 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

217. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

218. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '206 patent.

**COUNT 8**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,610,516)**

219. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 218 as if fully set forth herein.

220. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

221. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

222. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '516 patent.

223. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

224. The '516 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

225. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '516 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

226. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

227. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '516 patent.

**COUNT 9**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,620,918)**

228. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 227 as if fully set forth herein.

229. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

230. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

231. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '918 patent.

232. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

233. The '918 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

234. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '918 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

235. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

236. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '918 patent.

**COUNT 10**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,716,602)**

237. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 236 as if fully set forth herein.

238. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

239. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

240. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '602 patent.

241. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

242. The '602 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

243. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '602 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

244. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

245. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless

Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’602 patent.

**COUNT 11**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,381,560)**

246. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 245 as if fully set forth herein.

247. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

248. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

249. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’560 patent.

250. On account of Celltrion’s failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

251. The ’560 patent claims compositions used in and methods of making a therapeutic antibody product such as Truxima/CT-P10.

252. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’560 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

253. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

254. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '560 patent.

**COUNT 12**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,390,660)**

255. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 254 as if fully set forth herein.

256. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

257. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

258. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '660 patent.

259. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

260. The '660 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

261. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '660 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

262. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

263. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '660 patent.

**COUNT 13**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,485,704)**

264. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 263 as if fully set forth herein.

265. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

266. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

267. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '704 patent.

268. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

269. The '704 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

270. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '704 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

271. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

272. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '704 patent.

**COUNT 14**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,682,612)**

273. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 272 as if fully set forth herein.

274. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

275. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

276. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '612 patent.

277. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

278. The ’612 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

279. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’612 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

280. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

281. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’612 patent.

**COUNT 15**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,807,799)**

282. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 281 as if fully set forth herein.

283. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

284. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

285. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’799 patent.

286. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

287. The '799 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

288. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '799 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

289. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

290. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '799 patent.

**COUNT 16**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,820,161)**

291. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 290 as if fully set forth herein.

292. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

293. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

294. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale,

and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '161 patent.

295. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

296. The '161 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

297. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '161 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

298. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

299. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '161 patent.

**COUNT 17**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,923,221)**

300. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 299 as if fully set forth herein.

301. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

302. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

303. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '221 patent.

304. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

305. The '221 patent claims compositions used in and methods of making a therapeutic antibody product such as Truxima/CT-P10.

306. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '221 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

307. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

308. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '221 patent.

**COUNT 18**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,976,838)**

309. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 308 as if fully set forth herein.

310. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

311. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10

if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

312. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '838 patent.

313. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

314. The '838 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

315. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '838 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

316. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

317. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '838 patent.

**COUNT 19**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,044,017)**

318. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 317 as if fully set forth herein.

319. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

320. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

321. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '017 patent.

322. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

323. The '017 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

324. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '017 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

325. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

326. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '017 patent.

**COUNT 20**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,206,711)**

327. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 326 as if fully set forth herein.

328. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

329. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

330. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '711 patent.

331. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

332. The '711 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

333. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '711 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

334. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

335. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '711 patent.

**COUNT 21**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,329,172)**

336. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 335 as if fully set forth herein.

337. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

338. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

339. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '172 patent.

340. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

341. The '172 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

342. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '172 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

343. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

344. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless

Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '172 patent.

**COUNT 22**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,357,301)**

345. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 344 as if fully set forth herein.

346. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

347. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

348. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '301 patent.

349. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

350. The '301 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

351. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '301 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

352. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

353. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '301 patent.

**COUNT 23**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,460,895)**

354. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 353 as if fully set forth herein.

355. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

356. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

357. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '895 patent.

358. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

359. The '895 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

360. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '895 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

361. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

362. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '895 patent.

**COUNT 24**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,512,983)**

363. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 362 as if fully set forth herein.

364. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

365. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

366. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '983 patent.

367. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

368. The '983 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

369. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '983 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

370. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

371. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '983 patent.

**COUNT 25**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,545,843)**

372. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 371 as if fully set forth herein.

373. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

374. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

375. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '843 patent.

376. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

377. The ’843 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

378. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’843 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

379. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

380. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’843 patent.

**COUNT 26**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,557,244)**

381. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 380 as if fully set forth herein.

382. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

383. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

384. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’244 patent.

385. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

386. The '244 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

387. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '244 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

388. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

389. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '244 patent.

**COUNT 27**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,574,869)**

390. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 389 as if fully set forth herein.

391. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

392. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

393. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale,

and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '869 patent.

394. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

395. The '869 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

396. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '869 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

397. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

398. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '869 patent.

**COUNT 28**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,633,302)**

399. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 398 as if fully set forth herein.

400. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

401. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

402. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '302 patent.

403. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

404. The '302 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

405. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '302 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

406. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

407. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '302 patent.

**COUNT 29**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,710,196)**

408. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 407 as if fully set forth herein.

409. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

410. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10

if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

411. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '196 patent.

412. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

413. The '196 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

414. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '196 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

415. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

416. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '196 patent.

**COUNT 30**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,771,988)**

417. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 416 as if fully set forth herein.

418. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

419. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

420. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '988 patent.

421. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

422. The '988 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

423. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '988 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

424. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

425. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '988 patent.

**COUNT 31**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,821,873)**

426. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 425 as if fully set forth herein.

427. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

428. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

429. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '873 patent.

430. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

431. The '873 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

432. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '873 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

433. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

434. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '873 patent.

**COUNT 32**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,822,655)**

435. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 434 as if fully set forth herein.

436. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

437. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

438. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '655 patent.

439. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

440. The '655 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

441. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '655 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

442. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

443. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless

Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’655 patent.

**COUNT 33**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,047,438)**

444. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 443 as if fully set forth herein.

445. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

446. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

447. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’438 patent.

448. On account of Celltrion’s failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

449. The ’438 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

450. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’438 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

451. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

452. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '438 patent.

**COUNT 34**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,080,183)**

453. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 452 as if fully set forth herein.

454. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

455. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

456. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '183 patent.

457. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

458. The '183 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

459. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '183 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

460. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

461. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '183 patent.

**COUNT 35**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,296,821)**

462. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 461 as if fully set forth herein.

463. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

464. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

465. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '821 patent.

466. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

467. The '821 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

468. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '821 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

469. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

470. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '821 patent.

**COUNT 36**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,428,548)**

471. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 470 as if fully set forth herein.

472. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

473. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

474. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '548 patent.

475. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

476. The ’548 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

477. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the ’548 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

478. Defendants’ infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants’ wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

479. Moreover, Defendants’ infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the ’548 patent.

**COUNT 37**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,428,766)**

480. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 479 as if fully set forth herein.

481. The FDA has publicly stated that the agency’s goal is to act upon an aBLA application within 10 months of receipt.

482. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

483. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the ’766 patent.

484. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

485. The '766 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

486. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '766 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

487. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

488. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '766 patent.

**COUNT 38**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,487,809)**

489. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 488 as if fully set forth herein.

490. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

491. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

492. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale,

and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '809 patent.

493. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

494. The '809 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

495. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '809 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

496. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

497. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '809 patent.

**COUNT 39**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,504,744)**

498. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 497 as if fully set forth herein.

499. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

500. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

501. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '744 patent.

502. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

503. The '744 patent claims methods of using a therapeutic antibody product such as Truxima/CT-P10.

504. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '744 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

505. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

506. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '744 patent.

**COUNT 40**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,714,293)**

507. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 506 as if fully set forth herein.

508. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

509. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10

if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities

510. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the '293 patent.

511. On account of Celltrion's failure to comply with the requirements of 42 U.S.C. § 262(l), Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) and/or § 262(l)(9)(B) to bring this action.

512. The '293 patent claims methods of making a therapeutic antibody product such as Truxima/CT-P10.

513. Plaintiffs are entitled to a judicial declaration that Defendants have or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '293 patent under 35 U.S.C. 271(a), (b), (c), and/or (g).

514. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

515. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Defendants, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, are enjoined from any and all activities that would infringe the claims of the '293 patent.

**COUNT 41**

**(INFRINGEMENT OF U.S. PATENT NO. 6,121,428 UNDER 35 U.S.C. § 271(E)(2))**

516. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 515 as if fully set forth herein.

517. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the

commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

518. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

519. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

520. In the alternative and/or in addition to the declaratory judgment of infringement in Count 1, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '428 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

521. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '428 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

522. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '428 patent, with knowledge that the resulting conduct would infringe one or more claims of the '428 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '428 patent.

523. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '428 patent, including because Celltrion has

extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

524. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '428 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '428 patent.

525. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '428 patent, with knowledge that the resulting conduct would infringe one or more claims of the '428 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '428 patent.

526. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

527. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '428 patent. *See* 35 U.S.C. § 271(e)(4)(B).

528. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '428 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

529. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '428 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 42**

**(INFRINGEMENT OF U.S. PATENT NO. 6,242,177 UNDER 35 U.S.C. § 271(E)(2))**

530. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 529 as if fully set forth herein.

531. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

532. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

533. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

534. In the alternative and/or in addition to the declaratory judgment of infringement in Count 2, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '177 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

535. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '177 patent by actively inducing infringement of

one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

536. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '177 patent, with knowledge that the resulting conduct would infringe one or more claims of the '177 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '177 patent.

537. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '177 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

538. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '177 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '177 patent.

539. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '177 patent, with knowledge that the resulting conduct would infringe one or more claims of the '177 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '177 patent.

540. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

541. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '177 patent. *See* 35 U.S.C. § 271(e)(4)(B).

542. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '177 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

543. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '177 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 43**

**(INFRINGEMENT OF U.S. PATENT NO. 6,331,415 UNDER 35 U.S.C. § 271(E)(2))**

544. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 543 as if fully set forth herein.

545. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

546. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

547. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

548. In the alternative and/or in addition to the declaratory judgment of infringement in Count 3, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '415 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

549. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '415 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

550. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '415 patent, with knowledge that the resulting conduct would infringe one or more claims of the '415 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '415 patent.

551. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '415 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

552. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '415 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '415 patent.

553. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '415 patent, with knowledge that the resulting conduct would infringe one or more claims of the '415 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '415 patent.

554. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

555. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '415 patent. *See* 35 U.S.C. § 271(e)(4)(B).

556. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '415 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

557. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '415 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 44**

**(INFRINGEMENT OF U.S. PATENT NO. 6,417,335 UNDER 35 U.S.C. § 271(E)(2))**

558. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 557 as if fully set forth herein.

559. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

560. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

561. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

562. In the alternative and/or in addition to the declaratory judgment of infringement in Count 4, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '335 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

563. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '335 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

564. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '335 patent, with knowledge that the resulting conduct would infringe one or more claims of the '335 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '335 patent.

565. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '335 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

566. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '335 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '335 patent.

567. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '335 patent, with knowledge that the resulting conduct would infringe one or more claims of the '335 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '335 patent.

568. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

569. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '335 patent. *See* 35 U.S.C. § 271(e)(4)(B).

570. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '335 patent and its infringement thereof, Defendants willfully,

wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

571. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '335 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 45**

**(INFRINGEMENT OF U.S. PATENT NO. 6,455,043 UNDER 35 U.S.C. § 271(E)(2))**

572. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 571 as if fully set forth herein.

573. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

574. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

575. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

576. In the alternative and/or in addition to the declaratory judgment of infringement in Count 5, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '043 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

577. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '043 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

578. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '043 patent, with knowledge that the resulting conduct would infringe one or more claims of the '043 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '043 patent.

579. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '043 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

580. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '043 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '043 patent.

581. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '043 patent, with knowledge that the resulting conduct would infringe one or more claims of the '043 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '043 patent.

582. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants'

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

583. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '043 patent. *See* 35 U.S.C. § 271(e)(4)(B).

584. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '043 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

585. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '043 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 46**

**(INFRINGEMENT OF U.S. PATENT NO. 6,489,447 UNDER 35 U.S.C. § 271(E)(2))**

586. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 585 as if fully set forth herein.

587. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

588. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

589. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10

if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

590. In the alternative and/or in addition to the declaratory judgment of infringement in Count 6, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '447 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

591. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '447 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

592. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '447 patent, with knowledge that the resulting conduct would infringe one or more claims of the '447patent, and with the specific intent that the resulting conduct infringe one or more claims of the '447 patent.

593. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '447 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

594. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '447 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or

under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '447 patent.

595. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '447 patent, with knowledge that the resulting conduct would infringe one or more claims of the '447 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '447 patent.

596. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

597. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '447 patent. *See* 35 U.S.C. § 271(e)(4)(B).

598. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '447 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

599. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '447 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 47**

**(INFRINGEMENT OF U.S. PATENT NO. 6,586,206 UNDER 35 U.S.C. § 271(E)(2))**

600. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 599 as if fully set forth herein.

601. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

602. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

603. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

604. In the alternative and/or in addition to the declaratory judgment of infringement in Count 7, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '206 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

605. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '206 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

606. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '206 patent, with knowledge that the resulting conduct would infringe one or more claims of the '206 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '206 patent.

607. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '206 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

608. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '206 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '206 patent.

609. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '206 patent, with knowledge that the resulting conduct would infringe one or more claims of the '206 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '206 patent.

610. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

611. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or

participation with them, are enjoined from any and all activities that would infringe the claims of the '206 patent. *See* 35 U.S.C. § 271(e)(4)(B).

612. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '206 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

613. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '206 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 48**

**(INFRINGEMENT OF U.S. PATENT NO. 6,610,516 UNDER 35 U.S.C. § 271(E)(2))**

614. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 613 as if fully set forth herein.

615. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

616. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

617. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

618. In the alternative and/or in addition to the declaratory judgment of infringement in Count 8, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '516 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for

Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

619. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '516 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

620. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '516 patent, with knowledge that the resulting conduct would infringe one or more claims of the '516 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '516 patent.

621. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '516 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

622. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '516 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '516 patent.

623. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '516 patent, with knowledge that the resulting conduct would infringe one or more claims of the

'516 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '516 patent.

624. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

625. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '516 patent. *See* 35 U.S.C. § 271(e)(4)(B).

626. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '516 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

627. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '516 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 49**

**(INFRINGEMENT OF U.S. PATENT NO. 6,620,918 UNDER 35 U.S.C. § 271(E)(2))**

628. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 627 as if fully set forth herein.

629. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

630. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

631. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

632. In the alternative and/or in addition to the declaratory judgment of infringement in Count 9, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '918 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

633. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '918 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

634. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '918 patent, with knowledge that the resulting conduct would infringe one or more claims of the '918 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '918 patent.

635. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '918 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by

numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

636. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '918 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '918 patent.

637. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '918 patent, with knowledge that the resulting conduct would infringe one or more claims of the '918 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '918 patent.

638. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

639. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '918 patent. *See* 35 U.S.C. § 271(e)(4)(B).

640. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '918 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

641. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '918 patent justifies an injunction and an

award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 50**

**(INFRINGEMENT OF U.S. PATENT NO. 6,716,602 UNDER 35 U.S.C. § 271(E)(2))**

642. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 641 as if fully set forth herein.

643. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

644. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

645. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

646. In the alternative and/or in addition to the declaratory judgment of infringement in Count 10, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '602 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

647. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '602 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers,

distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

648. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '602 patent, with knowledge that the resulting conduct would infringe one or more claims of the '602 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '602 patent.

649. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '602 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

650. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '602 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '602 patent.

651. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '602 patent, with knowledge that the resulting conduct would infringe one or more claims of the '602 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '602 patent.

652. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

653. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless

Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '602 patent. *See* 35 U.S.C. § 271(e)(4)(B).

654. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '602 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

655. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '602 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 51**

**(INFRINGEMENT OF U.S. PATENT NO. 7,381,560 UNDER 35 U.S.C. § 271(E)(2))**

656. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 655 as if fully set forth herein.

657. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

658. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

659. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

660. In the alternative and/or in addition to the declaratory judgment of infringement in Count 11, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has

infringed one or more claims of the '560 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

661. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '560 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

662. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '560 patent, with knowledge that the resulting conduct would infringe one or more claims of the '560 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '560 patent.

663. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '560 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

664. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '560 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '560 patent.

665. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the

'560 patent, with knowledge that the resulting conduct would infringe one or more claims of the '560 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '560 patent.

666. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

667. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '560 patent. *See* 35 U.S.C. § 271(e)(4)(B).

668. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '560 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

669. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '560 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 52**

**(INFRINGEMENT OF U.S. PATENT NO. 7,390,660 UNDER 35 U.S.C. § 271(E)(2))**

670. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 669 as if fully set forth herein.

671. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the

commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

672. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

673. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

674. In the alternative and/or in addition to the declaratory judgment of infringement in Count 12, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '660 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

675. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '660 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

676. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '660 patent, with knowledge that the resulting conduct would infringe one or more claims of the '660 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '660 patent.

677. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '660 patent, including because Celltrion has

extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

678. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '660 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '660 patent.

679. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '660 patent, with knowledge that the resulting conduct would infringe one or more claims of the '660 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '660 patent.

680. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

681. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '660 patent. *See* 35 U.S.C. § 271(e)(4)(B).

682. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '660 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

683. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '660 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 53**

**(INFRINGEMENT OF U.S. PATENT NO. 7,485,704 UNDER 35 U.S.C. § 271(E)(2))**

684. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 683 as if fully set forth herein.

685. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

686. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

687. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

688. In the alternative and/or in addition to the declaratory judgment of infringement in Count 13, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '704 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

689. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '704 patent by actively inducing infringement of

one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

690. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '704 patent, with knowledge that the resulting conduct would infringe one or more claims of the '704 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '704 patent.

691. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '704 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

692. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '704 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '704 patent.

693. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '704 patent, with knowledge that the resulting conduct would infringe one or more claims of the '704 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '704 patent.

694. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

695. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '704 patent. *See* 35 U.S.C. § 271(e)(4)(B).

696. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '704 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

697. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '704 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 54**

**(INFRINGEMENT OF U.S. PATENT NO. 7,682,612 UNDER 35 U.S.C. § 271(E)(2))**

698. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 697 as if fully set forth herein.

699. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

700. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

701. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

702. In the alternative and/or in addition to the declaratory judgment of infringement in Count 14, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '612 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

703. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '612 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

704. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '612 patent, with knowledge that the resulting conduct would infringe one or more claims of the '612 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '612 patent.

705. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '612 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

706. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '612 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '612 patent.

707. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '612 patent, with knowledge that the resulting conduct would infringe one or more claims of the '612 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '612 patent.

708. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

709. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '612 patent. *See* 35 U.S.C. § 271(e)(4)(B).

710. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '612 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

711. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '612 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 55**

**(INFRINGEMENT OF U.S. PATENT NO. 7,807,799 UNDER 35 U.S.C. § 271(E)(2))**

712. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 711 as if fully set forth herein.

713. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

714. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

715. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

716. In the alternative and/or in addition to the declaratory judgment of infringement in Count 15, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '799 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

717. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '799 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

718. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '799 patent, with knowledge that the resulting conduct would infringe one or more claims of the '799 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '799 patent.

719. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '799 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

720. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '799 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '799 patent.

721. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '799 patent, with knowledge that the resulting conduct would infringe one or more claims of the '799 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '799 patent.

722. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

723. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '799 patent. *See* 35 U.S.C. § 271(e)(4)(B).

724. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '799 patent and its infringement thereof, Defendants willfully,

wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

725. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '799 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 56**

**(INFRINGEMENT OF U.S. PATENT NO. 7,820,161 UNDER 35 U.S.C. § 271(E)(2))**

726. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 725 as if fully set forth herein.

727. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

728. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

729. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

730. In the alternative and/or in addition to the declaratory judgment of infringement in Count 16, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '161 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

731. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '161 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

732. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '161 patent, with knowledge that the resulting conduct would infringe one or more claims of the '161 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '161 patent.

733. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '161 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

734. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '161 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '161 patent.

735. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '161 patent, with knowledge that the resulting conduct would infringe one or more claims of the '161 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '161 patent.

736. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants'

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

737. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '161 patent. *See* 35 U.S.C. § 271(e)(4)(B).

738. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '161 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

739. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '161 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 57**

**(INFRINGEMENT OF U.S. PATENT NO. 7,923,221 UNDER 35 U.S.C. § 271(E)(2))**

740. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 739 as if fully set forth herein.

741. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

742. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

743. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10

if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

744. In the alternative and/or in addition to the declaratory judgment of infringement in Count 17, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '221 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

745. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '221 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

746. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '221 patent, with knowledge that the resulting conduct would infringe one or more claims of the '221 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '221 patent.

747. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '221 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

748. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '221 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or

under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '221 patent.

749. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '221 patent, with knowledge that the resulting conduct would infringe one or more claims of the '221 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '221 patent.

750. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

751. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '221 patent. *See* 35 U.S.C. § 271(e)(4)(B).

752. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '221 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

753. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '221 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 58**

**(INFRINGEMENT OF U.S. PATENT NO. 7,976,838 UNDER 35 U.S.C. § 271(E)(2))**

754. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 753 as if fully set forth herein.

755. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

756. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

757. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

758. In the alternative and/or in addition to the declaratory judgment of infringement in Count 18, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '838 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

759. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '838 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

760. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '838 patent, with knowledge that the resulting conduct would infringe one or more claims of the '838 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '838 patent.

761. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '838 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

762. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '838 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '838 patent.

763. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '838 patent, with knowledge that the resulting conduct would infringe one or more claims of the '838 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '838 patent.

764. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

765. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or

participation with them, are enjoined from any and all activities that would infringe the claims of the '838 patent. *See* 35 U.S.C. § 271(e)(4)(B).

766. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '838 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

767. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '838 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 59**

**(INFRINGEMENT OF U.S. PATENT NO. 8,044,017 UNDER 35 U.S.C. § 271(E)(2))**

768. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 767 as if fully set forth herein.

769. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

770. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

771. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

772. In the alternative and/or in addition to the declaratory judgment of infringement in Count 19, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '017 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA

for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

773. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '017 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

774. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '017 patent, with knowledge that the resulting conduct would infringe one or more claims of the '017 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '017 patent.

775. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '017 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

776. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '017 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '017 patent.

777. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '017 patent, with knowledge that the resulting conduct would infringe one or more claims of the

'017 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '017 patent.

778. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

779. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '017 patent. *See* 35 U.S.C. § 271(e)(4)(B).

780. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '017 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

781. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '017 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 60**

**(INFRINGEMENT OF U.S. PATENT NO. 8,206,711 UNDER 35 U.S.C. § 271(E)(2))**

782. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 781 as if fully set forth herein.

783. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

784. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

785. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

786. In the alternative and/or in addition to the declaratory judgment of infringement in Count 20, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '711 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

787. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '711 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

788. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '711 patent, with knowledge that the resulting conduct would infringe one or more claims of the '711 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '711 patent.

789. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '711 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by

numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

790. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '711 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '711 patent.

791. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '711 patent, with knowledge that the resulting conduct would infringe one or more claims of the '711 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '711 patent.

792. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

793. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '711 patent. *See* 35 U.S.C. § 271(e)(4)(B).

794. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '711 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

795. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '711 patent justifies an injunction and an

award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 61**

**(INFRINGEMENT OF U.S. PATENT NO. 8,329,172 UNDER 35 U.S.C. § 271(E)(2))**

796. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 795 as if fully set forth herein.

797. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

798. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

799. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

800. In the alternative and/or in addition to the declaratory judgment of infringement in Count 21, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '172 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

801. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '172 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers,

distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

802. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '172 patent, with knowledge that the resulting conduct would infringe one or more claims of the '172 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '172 patent.

803. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '172 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

804. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '172 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '172 patent.

805. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '172 patent, with knowledge that the resulting conduct would infringe one or more claims of the '172 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '172 patent.

806. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

807. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless

Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '172 patent. *See* 35 U.S.C. § 271(e)(4)(B).

808. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '172 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

809. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '172 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 62**

**(INFRINGEMENT OF U.S. PATENT NO. 8,357,301 UNDER 35 U.S.C. § 271(E)(2))**

810. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 809 as if fully set forth herein.

811. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

812. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

813. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

814. In the alternative and/or in addition to the declaratory judgment of infringement in Count 22, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has

infringed one or more claims of the '301 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

815. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '301 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

816. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '301 patent, with knowledge that the resulting conduct would infringe one or more claims of the '301 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '301 patent.

817. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '301 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

818. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '301 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '301 patent.

819. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the

'301 patent, with knowledge that the resulting conduct would infringe one or more claims of the '301 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '301 patent.

820. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

821. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '301 patent. *See* 35 U.S.C. § 271(e)(4)(B).

822. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '301 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

823. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '301 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 63**

**(INFRINGEMENT OF U.S. PATENT NO. 8,460,895 UNDER 35 U.S.C. § 271(E)(2))**

824. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 823 as if fully set forth herein.

825. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the

commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

826. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

827. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

828. In the alternative and/or in addition to the declaratory judgment of infringement in Count 23, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '895 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

829. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '895 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

830. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '895 patent, with knowledge that the resulting conduct would infringe one or more claims of the '895 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '895 patent.

831. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '895 patent, including because Celltrion has

extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

832. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '895 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '895 patent.

833. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '895 patent, with knowledge that the resulting conduct would infringe one or more claims of the '895 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '895 patent.

834. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

835. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '895 patent. *See* 35 U.S.C. § 271(e)(4)(B).

836. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '895 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

837. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '895 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 64**

**(INFRINGEMENT OF U.S. PATENT NO. 8,512,983 UNDER 35 U.S.C. § 271(E)(2))**

838. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 837 as if fully set forth herein.

839. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

840. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

841. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

842. In the alternative and/or in addition to the declaratory judgment of infringement in Count 24, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

843. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '983 patent by actively inducing infringement of

one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

844. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '983 patent, with knowledge that the resulting conduct would infringe one or more claims of the '983 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '983 patent.

845. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '983 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

846. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '983 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '983 patent.

847. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '983 patent, with knowledge that the resulting conduct would infringe one or more claims of the '983 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '983 patent.

848. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

849. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '983 patent. *See* 35 U.S.C. § 271(e)(4)(B).

850. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '983 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

851. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '983 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 65**

**(INFRINGEMENT OF U.S. PATENT NO. 8,545,843 UNDER 35 U.S.C. § 271(E)(2))**

852. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 851 as if fully set forth herein.

853. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

854. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

855. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

856. In the alternative and/or in addition to the declaratory judgment of infringement in Count 25, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '843 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

857. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '843 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

858. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '843 patent, with knowledge that the resulting conduct would infringe one or more claims of the '843 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '843 patent.

859. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '843 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

860. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '843 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '843 patent.

861. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '843 patent, with knowledge that the resulting conduct would infringe one or more claims of the '843 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '843 patent.

862. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

863. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '843 patent. *See* 35 U.S.C. § 271(e)(4)(B).

864. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '843 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

865. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '843 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 66**

**(INFRINGEMENT OF U.S. PATENT NO. 8,557,244 UNDER 35 U.S.C. § 271(E)(2))**

866. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 865 as if fully set forth herein.

867. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

868. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

869. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

870. In the alternative and/or in addition to the declaratory judgment of infringement in Count 26, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '244 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

871. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '244 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

872. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '244 patent, with knowledge that the resulting conduct would infringe one or more claims of the '244 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '244 patent.

873. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '244 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

874. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '244 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '244 patent.

875. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '244 patent, with knowledge that the resulting conduct would infringe one or more claims of the '244 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '244 patent.

876. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

877. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '244 patent. *See* 35 U.S.C. § 271(e)(4)(B).

878. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '244 patent and its infringement thereof, Defendants willfully,

wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

879. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '244 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 67**

**(INFRINGEMENT OF U.S. PATENT NO. 8,574,869 UNDER 35 U.S.C. § 271(E)(2))**

880. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 879 as if fully set forth herein.

881. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

882. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

883. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

884. In the alternative and/or in addition to the declaratory judgment of infringement in Count 27, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '869 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

885. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '869 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

886. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '869 patent, with knowledge that the resulting conduct would infringe one or more claims of the '869 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '869 patent.

887. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '869 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

888. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '869 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '869 patent.

889. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '869 patent, with knowledge that the resulting conduct would infringe one or more claims of the '869 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '869 patent.

890. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants'

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

891. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '869 patent. *See* 35 U.S.C. § 271(e)(4)(B).

892. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '869 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

893. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '869 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 68**

**(INFRINGEMENT OF U.S. PATENT NO. 8,633,302 UNDER 35 U.S.C. § 271(E)(2))**

894. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 893 as if fully set forth herein.

895. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

896. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

897. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10

if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

898. In the alternative and/or in addition to the declaratory judgment of infringement in Count 28, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '302 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

899. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '302 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

900. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '302 patent, with knowledge that the resulting conduct would infringe one or more claims of the '302 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '302 patent.

901. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '302 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

902. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '302 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or

under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '302 patent.

903. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '302 patent, with knowledge that the resulting conduct would infringe one or more claims of the '302 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '302 patent.

904. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

905. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '302 patent. *See* 35 U.S.C. § 271(e)(4)(B).

906. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '302 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

907. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '302 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 69**

**(INFRINGEMENT OF U.S. PATENT NO. 8,710,196 UNDER 35 U.S.C. § 271(E)(2))**

908. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 907 as if fully set forth herein.

909. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

910. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

911. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

912. In the alternative and/or in addition to the declaratory judgment of infringement in Count 29, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '196 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

913. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '196 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

914. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '196 patent, with knowledge that the resulting conduct would infringe one or more claims of the '196 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '196 patent.

915. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '196 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

916. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '196 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '196 patent.

917. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '196 patent, with knowledge that the resulting conduct would infringe one or more claims of the '196 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '196 patent.

918. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

919. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or

participation with them, are enjoined from any and all activities that would infringe the claims of the '196 patent. *See* 35 U.S.C. § 271(e)(4)(B).

920. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '196 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

921. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '196 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 70**

**(INFRINGEMENT OF U.S. PATENT NO. 8,771,988 UNDER 35 U.S.C. § 271(E)(2))**

922. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 921 as if fully set forth herein.

923. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

924. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

925. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

926. In the alternative and/or in addition to the declaratory judgment of infringement in Count 30, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '988 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA

for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

927. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '988 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

928. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '988 patent, with knowledge that the resulting conduct would infringe one or more claims of the '988 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '988 patent.

929. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '988 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

930. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '988 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '988 patent.

931. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '988 patent, with knowledge that the resulting conduct would infringe one or more claims of the

'988 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '988 patent.

932. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

933. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '988 patent. *See* 35 U.S.C. § 271(e)(4)(B).

934. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '988 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

935. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '988 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 71**

**(INFRINGEMENT OF U.S. PATENT NO. 8,821,873 UNDER 35 U.S.C. § 271(E)(2))**

936. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 935 as if fully set forth herein.

937. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

938. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

939. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

940. In the alternative and/or in addition to the declaratory judgment of infringement in Count 31, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '873 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

941. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '873 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

942. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '873 patent, with knowledge that the resulting conduct would infringe one or more claims of the '873 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '873 patent.

943. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '873 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by

numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

944. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '873 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '873 patent.

945. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '873 patent, with knowledge that the resulting conduct would infringe one or more claims of the '873 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '873 patent.

946. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

947. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '873 patent. *See* 35 U.S.C. § 271(e)(4)(B).

948. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '873 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

949. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '873 patent justifies an injunction and an

award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 72**

**(INFRINGEMENT OF U.S. PATENT NO. 8,822,655 UNDER 35 U.S.C. § 271(E)(2))**

950. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 949 as if fully set forth herein.

951. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

952. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

953. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

954. In the alternative and/or in addition to the declaratory judgment of infringement in Count 32, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '655 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

955. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '655 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers,

distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

956. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '655 patent, with knowledge that the resulting conduct would infringe one or more claims of the '655 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '655 patent.

957. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '655 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

958. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '655 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '655 patent.

959. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '655 patent, with knowledge that the resulting conduct would infringe one or more claims of the '655 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '655 patent.

960. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

961. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless

Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '655 patent. *See* 35 U.S.C. § 271(e)(4)(B).

962. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '655 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

963. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '655 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 73**

**(INFRINGEMENT OF U.S. PATENT NO. 9,047,438 UNDER 35 U.S.C. § 271(E)(2))**

964. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 963 as if fully set forth herein.

965. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

966. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

967. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

968. In the alternative and/or in addition to the declaratory judgment of infringement in Count 33, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has

infringed one or more claims of the '438 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

969. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '438 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

970. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '438 patent, with knowledge that the resulting conduct would infringe one or more claims of the '438 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '438 patent.

971. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '438 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

972. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '438 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '438 patent.

973. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the

'438 patent, with knowledge that the resulting conduct would infringe one or more claims of the '438 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '438 patent.

974. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

975. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '438 patent. *See* 35 U.S.C. § 271(e)(4)(B).

976. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '438 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

977. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '438 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 74**

**(INFRINGEMENT OF U.S. PATENT NO. 9,080,183 UNDER 35 U.S.C. § 271(E)(2))**

978. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 977 as if fully set forth herein.

979. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the

commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

980. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

981. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

982. In the alternative and/or in addition to the declaratory judgment of infringement in Count 34, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '183 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

983. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '183 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

984. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '183 patent, with knowledge that the resulting conduct would infringe one or more claims of the '183 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '183 patent.

985. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '183 patent, including because Celltrion has

extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

986. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '183 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '183 patent.

987. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '183 patent, with knowledge that the resulting conduct would infringe one or more claims of the '183 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '183 patent.

988. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

989. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '183 patent. *See* 35 U.S.C. § 271(e)(4)(B).

990. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '183 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

991. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '183 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 75**

**(INFRINGEMENT OF U.S. PATENT NO. 9,296,821 UNDER 35 U.S.C. § 271(E)(2))**

992. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 991 as if fully set forth herein.

993. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

994. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

995. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

996. In the alternative and/or in addition to the declaratory judgment of infringement in Count 35, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '821 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

997. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '821 patent by actively inducing infringement of

one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

998. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '821 patent, with knowledge that the resulting conduct would infringe one or more claims of the '821 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '821 patent.

999. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '821 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

1000. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '821 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '821 patent.

1001. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '821 patent, with knowledge that the resulting conduct would infringe one or more claims of the '821 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '821 patent.

1002. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

1003. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '821 patent. *See* 35 U.S.C. § 271(e)(4)(B).

1004. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '821 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

1005. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '821 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 76**

**(INFRINGEMENT OF U.S. PATENT NO. 9,428,548 UNDER 35 U.S.C. § 271(E)(2))**

1006. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 1005 as if fully set forth herein.

1007. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

1008. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

1009. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

1010. In the alternative and/or in addition to the declaratory judgment of infringement in Count 36, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '548 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

1011. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '548 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

1012. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '548 patent, with knowledge that the resulting conduct would infringe one or more claims of the '548 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '548 patent.

1013. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '548 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

1014. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '548 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '548 patent.

1015. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '548 patent, with knowledge that the resulting conduct would infringe one or more claims of the '548 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '548 patent.

1016. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

1017. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '548 patent. *See* 35 U.S.C. § 271(e)(4)(B).

1018. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '548 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

1019. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '548 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 77**

**(INFRINGEMENT OF U.S. PATENT NO. 9,428,766 UNDER 35 U.S.C. § 271(E)(2))**

1020. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 1019 as if fully set forth herein.

1021. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

1022. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

1023. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

1024. In the alternative and/or in addition to the declaratory judgment of infringement in Count 37, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '766 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

1025. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '766 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

1026. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '766 patent, with knowledge that the resulting conduct would infringe one or more claims of the '766 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '766 patent.

1027. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '766 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

1028. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '766 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '766 patent.

1029. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '766 patent, with knowledge that the resulting conduct would infringe one or more claims of the '766 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '766 patent.

1030. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

1031. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '766 patent. *See* 35 U.S.C. § 271(e)(4)(B).

1032. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '766 patent and its infringement thereof, Defendants willfully,

wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

1033. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '766 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 78**

**(INFRINGEMENT OF U.S. PATENT NO. 9,487,809 UNDER 35 U.S.C. § 271(E)(2))**

1034. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 1033 as if fully set forth herein.

1035. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

1036. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

1037. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

1038. In the alternative and/or in addition to the declaratory judgment of infringement in Count 38, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '809 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

1039. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '809 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

1040. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '809 patent, with knowledge that the resulting conduct would infringe one or more claims of the '809 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '809 patent.

1041. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '809 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

1042. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '809 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '809 patent.

1043. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '809 patent, with knowledge that the resulting conduct would infringe one or more claims of the '809 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '809 patent.

1044. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants'

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

1045. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '809 patent. *See* 35 U.S.C. § 271(e)(4)(B).

1046. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '809 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

1047. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '809 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 79**

**(INFRINGEMENT OF U.S. PATENT NO. 9,504,744 UNDER 35 U.S.C. § 271(E)(2))**

1048. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 1047 as if fully set forth herein.

1049. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

1050. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

1051. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10

if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

1052. In the alternative and/or in addition to the declaratory judgment of infringement in Count 39, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '744 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

1053. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '744 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

1054. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '744 patent, with knowledge that the resulting conduct would infringe one or more claims of the '744 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '744 patent.

1055. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '744 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

1056. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '744 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or

under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '744 patent.

1057. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '744 patent, with knowledge that the resulting conduct would infringe one or more claims of the '744 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '744 patent.

1058. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

1059. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or participation with them, are enjoined from any and all activities that would infringe the claims of the '744 patent. *See* 35 U.S.C. § 271(e)(4)(B).

1060. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '744 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

1061. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '744 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT 80**

**(INFRINGEMENT OF U.S. PATENT NO. 9,714,293 UNDER 35 U.S.C. § 271(E)(2))**

1062. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 1061 as if fully set forth herein.

1063. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Truxima/CT-P10, a proposed biosimilar version of Rituxan®.

1064. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Celltrion's aBLA for review on or about June 27, 2017.

1065. Plaintiffs are informed and believe, and on that basis allege, that Defendants intend to engage in the commercial manufacture, use, offer for sale, and sale of Truxima/CT-P10 if and when it receives FDA approval to do so, as well as to import Truxima/CT-P10 into the United States for those purposes; and induce and/or contribute to these activities.

1066. In the alternative and/or in addition to the declaratory judgment of infringement in Count 40, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has infringed one or more claims of the '293 patent under 35 U.S.C. § 271(e)(2) by filing its aBLA for Truxima/CT-P10 for the express purpose of making, using, offering for sale, selling, and/or importing Truxima/CT-P10 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

1067. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has further infringed, or will further infringe, the '293 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Truxima/CT-P10 without license or authority from Plaintiffs.

1068. Plaintiffs are informed and believe, and on that basis allege, that Celltrion has engaged and continues to engage in these acts with knowledge of the '293 patent, with knowledge that the resulting conduct would infringe one or more claims of the '293 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '293 patent.

1069. For example, Plaintiffs are informed and believe, and on that basis allege, that Celltrion has knowledge of and is aware of the '293 patent, including because Celltrion has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Celltrion has participated in the United States and worldwide.

1070. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have infringed, or will further infringe, the '293 patent under 35 U.S.C. § 271(b) by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing Celltrion's infringement of the '293 patent.

1071. Plaintiffs are informed and believe, and on that basis allege, that Teva, TPIG, and Celltrion Healthcare have engaged and continue to engage in these acts with knowledge of the '293 patent, with knowledge that the resulting conduct would infringe one or more claims of the '293 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '293 patent.

1072. Defendants' infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

1073. Moreover, Defendants' infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Defendants, together with each person and entity acting on their behalf or in active concert or

participation with them, are enjoined from any and all activities that would infringe the claims of the '293 patent. *See* 35 U.S.C. § 271(e)(4)(B).

1074. Plaintiffs are informed and believe, and on that basis allege, that despite Defendants' knowledge of the '293 patent and its infringement thereof, Defendants willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

1075. Plaintiffs are informed and believe, and on that basis allege, that Defendants' willful, wanton, and deliberate infringement of the '293 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for relief as follows:

A. A declaration that the manufacture, use, offer for sale, sale, and/or importation of Truxima/CT-P10 has or will infringe one or more claims of the Asserted Patents;

B. A declaration that the Asserted Patents are valid and enforceable;

C. An award of damages pursuant to 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284;

D. A declaration that Defendants' infringement was willful and deliberate, an injunction, and a three-fold increase in the award of any damages in accordance with 35 U.S.C. § 284;

E. An award for an accounting of damages from Defendants' infringement;

F. Preliminary and/or permanent injunctive relief, including pursuant to 35 U.S.C. § 271(e)(4)(B), including an order that Defendants and any of their affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for any of them and/or on any of their behalf, and other persons in active concert or participation with any of them directly and/or indirectly, be preliminarily and permanently enjoined from infringing, inducing others to infringe, or contributing to the infringement of the Asserted Patents;

G. An award to Plaintiffs of their costs and reasonable expenses to the fullest extent permitted by law;

H. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorneys' fees and costs pursuant to 35 U.S.C. § 285 and 35 U.S.C. § 271(e)(4); and

I. An award of such other and further relief as the Court may deem just and proper.

**JURY DEMAND**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs hereby demand trial by jury of all issues so triable by a jury in this action.

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| Dated: January 12, 2018<br><br>*Of Counsel:*<br><br>David I. Gindler<br>Gary N. Frischling<br>Keith A. Orso<br>IRELL & MANELLA LLP<br>1800 Avenue of the Stars, Suite 900<br>Los Angeles, CA 90067<br>Telephone: (310) 277-1010 | By: */s/ Keith J. Miller*<br>Keith J. Miller, Esq.<br>ROBINSON MILLER LLC<br>One Newark Center, 19th Floor<br>Newark, NJ 07102<br>Telephone: (973) 690-5400<br>kmiller@rwmlegal.com<br><br>*Attorneys for Plaintiffs Genentech, Inc., Biogen, Inc., Hoffmann-La Roche Inc., and City of Hope* |